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|-------------------------------|------------------------|---------------------|--|
| <b>Notice of Allowability</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                               | 10/663,853             | REDDY ET AL.        |  |
|                               | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                               | Anand U Desai, Ph.D.   | 1653                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to October 4, 2004.
2. ☒ The allowed claim(s) is/are 1-12, 14-19 and 21-31.
3. ☒ The drawings filed on 16 September 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|   | 9. <input type="checkbox"/> Other _____.   |

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### **DETAILED ACTION**

1. This office action is in response to Amendment filed on October 4, 2004. Claims 13, and 20 have been cancelled. New claims 30, and 31 have been added. Claims 1-12, 14-19, 21-31 are currently pending and are under examination.

### **Withdrawal of Rejections**

2. The rejection of claims 26, and 28 under 35 U.S.C. § 112, second paragraph is withdrawn based on Applicant's amendment.

3. The rejection of claims 1, 9, 10, 12, 14, 15, and 22 under 35 U.S.C. § 102 as being anticipated by Tanigawa et al. (Journal of Fermentation and Bioengineering, Vol. 75, No. 4, pp. 254-258 (1993)) is withdrawn based on Applicant's amendment.

4. The rejection of claims 1, 3, 4, 7, 9, 10, 12, 14, 15-18, and 22 under 35 U.S.C. § 103(a) as being unpatentable over Tanigawa et al. (Journal of Fermentation and Bioengineering, Vol. 75, No. 4, pp. 254-258 (1993)) is withdrawn based on Applicant's amendment.

5. The rejection of claims 1, 3, 4, 7-12, 14-18, 22, and 23 under 35 U.S.C. § 103(a) as being unpatentable over Tanigawa et al. (Journal of Fermentation and Bioengineering, Vol. 75, No. 4, pp. 254-258 (1993)) in view of Lucas et al. (Nucleic Acids Research Vol. 24, No. 9, pp. 1774-1779 (1996)) is withdrawn based on Applicant's amendment.

### **EXAMINER'S AMENDMENT**

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

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1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Rosemary Sweeney on October 26, 2004.

**Examiner's Amendment to the Specification:**

Please replace the Abstract with the following Abstract:

The invention provides a method for increasing production of a protein by cultured mammalian cells comprising adding a DNA demethylating agent, for example a cytidine analogue, to the mammalian cell culture. The cytidine analogue can be 5-aza-2'-deoxycytidine (also called decitabine) or 5-bromo-2'-deoxycytidine-5'-monophosphate, among many other possible cytidine analogues.

***Allowable Subject Matter***

7. Claims 1-12, 14-19, and 21-31 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

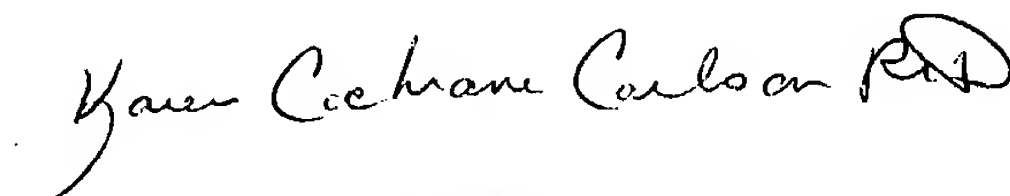
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 26, 2004

  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER